

REMARKS

In the Office Action dated June 23, 2009, claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-49 were pending, all of which are rejected.

The drawings are objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) for including reference numeral “53” in Figure 8 but no mention of this reference number in the specification. Claims 7, 8, 11 and 12 are objected to for failing to provide sufficient antecedent basis. Claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-49 were rejected under 35 U.S.C. § 112, ¶ 1, as failing to comply with the enablement requirement.

Claims 3, 4, 8, 9, 12, 44, 46, 48, and 49 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,421,349 to Rodriguez et al. (“*Rodriguez*”) in view of U.S. Patent No. 5,584,803 to Stevens et al. (“*Stevens*”) and in further in view of U.S. Patent No. 6,086,548 to Chaisson et al. (“*Chaisson*”). Claims 28, 35, 45, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of *Stevens*, in further in view of *Chaisson*, and even further in view of U.S. Patent No. 6,165,140 to Ferrera (“*Ferrera*”). Claims 7 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of *Stevens*, in further in view of *Chaisson*, and even further in view of U.S. Patent No. 6,716,183 to Clayman et al. (“*Clayman*”). Claim 42 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez*, in view of *Stevens*, in further view of *Chaisson*, and even further in view of U.S. Patent No. 5,693,083 to Baker et al. (“*Baker*”) or U.S. Patent No. 6,354,550 to McNamara et al. (“*McNamara*”).

Dependent claims 7, 8, 11 and 12 have been amended. The amendments to these claims have been made for clarity purposes only and not for reasons related to patentability. The amendments changed the dependency of claims 7, 8, 11 and 12 and therefore no new matter has been added.

I. Examiner Interview

Applicants thank Examiners Towa and Hindenburg for their time and consideration during the telephonic interview of September 23, 2009. Present at the interview were Examiners Towa and Hindenburg, Applicants' representative from Cook, Inc., Richard J. Godlewski, and Janet A. Pioli and Manish K. Mehta of Brinks Hofer Gilson & Lione.

During the interview, Applicants' representatives discussed the primary reference, Rodriguez, et al., Patent No. 5,421,349 (Rodriguez) cited under 35 U.S.C. § 103, and explained how Rodriguez does not disclose each and every element of independent claims 48 and 49. As pointed out, Rodriguez wholly fails to disclose three distinct zones, including a proximal zone (closest to the physician), a distal zone (closest to the heart), and an elongate central zone. The distal zone and the proximal zone both transition **from** the highest stiffness central zone to an area of lesser stiffness. In particular, the distal zone (closest to the heart) transitions **from** the highest stiffness of elongate central zone through three distinct zones of decreasing stiffness (increasing flexibility). Wholly to the contrary, Figure 1 of Rodriguez shows only numeral 11 (which Rodriguez is wholly silent as to its stiffness or relative stiffness as to the rest of the guidewire 10), and PTFE coating 19 overlapping 11, which in the Figure is shown to be greater diameter than 11. As pointed out during the interview, if Examiner Towa's argument that the figures show a zone of decreasing stiffness merely based on the figures purportedly showing a tapered tip (or lesser diameter), then it must follow that reference numeral 19 (which is clearly shown of a greater thickness) must be more stiff and, hence, there is no teaching of a transition **from** a zone of highest stiffness through zones of decreasing stiffness. Applicants submit that Rodriguez teaches away from their invention.

Although no agreement was reached, Examiners Towa and Hindenburg agreed to consider Applicants' assertions.

II. Drawing Objections

The drawings have been objected to for failing to comply with 37 C.F.R. §1.84(p)(5) for failing to include reference character 53 in Figure 8 without any

corresponding reference character in the Specification. The Applicants have amended Paragraph [0071] to include reference character 53. Support for this amendment can be found in Figure 8 and in Paragraph [0071]. The applicants submit that the drawing objection has been obviated by the appropriate amendment to the specification and no new matter has been added.

III. Claim Objections

Claims 7, 8 and 11 and 12 have been objected for failing to provide sufficient antecedent basis. The Applicants have amended claims 7 and 8 such that they now depend from claim 4 and have amended claims 11 and 12 such that they now depend from claim 9. The Applicants respectfully request withdrawal of this objection. No new matter has been added.

IV. Claim Rejections – 35 U.S.C. § 112, ¶ 1

Claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-49 are rejected under 35 U.S.C. § 112, ¶ 1 for failing to comply with the enablement requirement. The Examiner contends that the claims contain subject matter which “was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention.” The Examiner argues that the Specification does not support “a semi-stiff zone having a high stiffness portion” because there is no support for a distinct zone “to simultaneously include two different stiffnesses” The Examiner explains that “it is clear that the zones are distinguished from each other by the mere fact that they each have a distinct particular stiffness as opposed to overlapping stiffnesses such that the guide wire as a whole has a smooth stiffness transition resulting from an incremental change in stiffness with each zone”

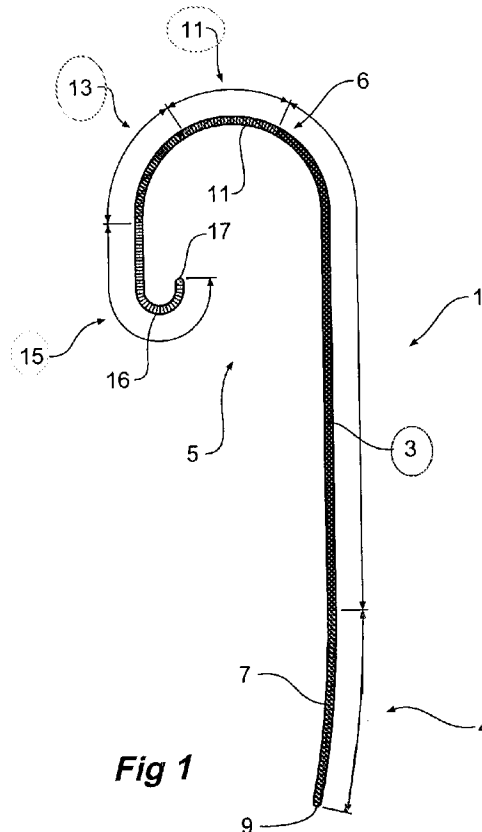
The Applicants respectfully disagree with the Examiner’s reasoning that the Specification does not enable one of ordinary skill in the art to make and/or use the invention. The Examiner relies on the argument that because the distinct zones are made out of the same material, they cannot have a transitional stiffness within each zone. Put another way the Examiner states that each zone cannot have more than one different stiffnesses because the “zones are distinguished from each other by the mere fact that [the zones] have a distinct particular stiffness as opposed to overlapping

stiffnesses” However, the Specification discloses that the mandrel of the guidewire having tapering portions, e.g. reference numbers 54 and 56, that permit the flexibility of the guidewire to change within a specific zone. (Specification, ¶ 71). The Specification further contemplates a method of construction where the mandrel is drawn down “to have decreasing diameter towards the distal end and towards the proximal end” (Specification ¶ 78), or where “the central member has a taper on the distal end that produces certain parts of the flexibility changes as well as a taper on the proximal end that produces the stiffness transitions at the proximal end.” (Specification, ¶ 79). Along with the taper, a spring coil can be added “to maintain diameter at the tapered proximal portion and to provide the correct flexibility” (Specification, ¶ 79). Therefore, the relationship between the tapering mandrel portions and the spring coil permit each “zone” to have more than one stiffness, and the claims 48 and 49 do not require the “semi-stiff zone” to have a high stiffness throughout the entire zone, but only “a proximal portion of high stiffness adjacent to the distal portion of the central zone.”

V. Rodriguez Does Not Disclose The Five Zones of Stiffness As Claimed

The Office Action states that the teachings of Rodriguez include the five zones of varying stiffness. Claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-47 depend either from independent claims 48 or 49. Each of these independent claims claim five distinct zones requiring different levels of flexibility. Claims 48 and 49 are reproduced above.

Annotated Figure 1 below illustrated each of the five claimed zones:

**Fig 1**

As clearly shown in annotated Figure 1, the claimed guidewire has five distinct zones. Zone 4, the proximal zone (shown in red); zone 3, the elongate central zone (shown in blue); and zone 5, which consists of three zones, 11 (shown in green), 13 (shown in pink) and 15 (shown in yellow). Zone 4 transitions from semi-stiff to the stiffness of central zone 2. Adjacent zone 3 is zone 5 which transitions from the high stiffness of zone 3 through the three zones of zone 5 to the most flexible (element number 15). Nowhere does Rodriguez disclose or even suggest a proximal zone that **transitions from semi-stiff to stiff**. Nowhere does Rodriguez disclose or even suggest an elongate zone of constant stiffness. Nowhere does Rodriguez disclose or even suggest a third zone that **transitions from the high stiffness of the central zone through three zones of increasing flexibility (decreasing stiffness) to the most flexible zone**.

Moreover, the Examiner's reliance on annotated Figure 1 to show the five distinct zones of Rodriguez is misfounded. Specifically, the Examiner cites to the annotated figure to support that Rodriguez discloses:

a distal zone adjacent to the high stiffness central zone having a proximal portion of high-stiffness **adjacent to** the distal portion of the central zone and transitioning to a distal portion of highest flexibility when the distal zone comprises three zones: a third semi stiff zone having a proximal portion of high stiffness **adjacent to** the distal portion of the central zone **transitioning to** a distal portion of semi-stiffnesses

(June 23, 2009 Office Action, pp. 5-6) (emphasis added).

Rodriguez's disclosure, however, regarding the flexibility of the distal end is limited to the following: "Guidewire 10 defines a distal tip 14, having a resilient, flexible tip which comprises a tapered down, thin portion 16 of the guidewire surrounded by a coil spring." (Col. 2, lines 66-68). Rodriguez further discloses a Polytetrafluoroethylene (PTFE) coating 19 that "is provided just adjacent to the tapered wire portion and slightly overlapping it." (Rodriguez, Col. 3, ll. 15-17). Further, as shown in Figure 1 of Rodriguez, the coating 19 is disposed adjacent to the main portion 11 and is between the main portion 11 and the distal end 14. In accordance with the Examiner's argument that Rodriguez must disclose the five zones of varying stiffness, as claimed, because Figure 1 of Rodriguez shows a decreasing tapering diameter of the distal end 14 and proximal end 20, the larger diameter of the coating 19 that is adjacent to, and between, the main portion 11 and distal end 14 must have a higher stiffness than the main portion 11, and the highest stiffness of the entire guidewire 10. Put simply, Rodriguez teaches an area (19) (which if accepting only for the sake of argument the Examiner's assertion that thicker diameter means less flexible) clearly shows no such transition from a zone of high stiffness to one of increasing flexibility.

Accordingly, Rodriguez does not teach or disclose the three zones within the distal zone or the respective stiffness of each of five zones as required by independent claim 48 and 49. This deficiency is not cured by the teachings of Stevens, Chaisson, Ferrera, Clayman, Baker, or McNamara, alone or in proper combination.

VII. Conclusion

In light of the above, Applicants submit that claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-49 are in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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